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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/192,579	11/17/1998	FRANCO MENOZZI	960-34	9973

7590 11/12/2003

NIXON AND VANDEHYDE
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ARLINGTON, VA 22201

EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/12/2003

35

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/192,579

Applicant(s)

MENOZZI ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22September2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-67 is/are rejected.
- 7) ☒ Claim(s) 68-70 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicants' Response to Office Action, received 22September2003, paper#33, is acknowledged.
2. Claims 56-70 are pending and under consideration.

Rejections Maintained

3. The rejection of claims 56-67 under 35 U.S.C. 102(b) as being anticipated by Menozzi et al (*Abstracts of the General Meeting of the ASM*, 95(0):193, abstract B-159) is maintained for the reasons put forth in the original rejection (Office Action, paper#20, mailed 9January2002) and upheld in examiner's responses to applicants' arguments (Office Action, paper#24, mailed 10October2002; Advisory, paper#27, mailed 13February2003; Advisory, paper#30, mailed 26March2003).

Applicants argue that even if a claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling. The cited reference is not enabling because it does not contain information: 1) to permit molecular characterization of the functional activity; 2) concerning amino acid sequence; and 3) concerning antibodies.

The examiner has considered applicants' argument, but does not find it persuasive. The instant claims are drawn to an isolated proteinic mycobacterial antigen comprising specific amino acid sequence and is recognizable by specific monoclonal antibodies. Support for the claims is provided by the teaching and more specifically by the examples in the specification. As stated in the Advisory Action, mailed 13February2003, in the absence of evidence to the contrary, Menozzi et al do teach the claimed proteinic mycobacterial antigen based upon the data that: 1) the instant inventors and their laboratories are also authors on the cited reference, 2) both proteins have the same name, 3) both proteins are from identical mycobacterial

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sources, and 4) both proteins have identical characteristics. The amino sequence of the cited reference HBHA and its binding to specific monoclonal antibodies would be identical to the HBHA of the instant claims. Applicants' argument has not put forth data indicating the contrary, i.e., the HBHA of the cited reference **is not** the claimed HBHA. Therefore, the rejection is maintained for reasons of record.

4. Claims 68-70 remain objected to as being dependent from rejected claims.

Conclusion

5. No claims are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

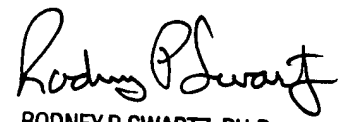
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

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If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.



RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

November 12, 2003